DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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From: Gini Guptill, PhD
Acting Director, Office of Research Support and Compliance
Jonathan Green, MD
Director Office of Human Subjects Research Protections

To: Institute and Center (IC) Clinical and Scientific Directors
All NIH Intramural Research Program (IRP) Clinical and Basic Research Investigators
IC Protocol Navigators
IC Quality Assurance Professionals

Subject: Memo – Witness Signature Block on Written Long Form Research Consents

On January 15, 2018, a memorandum was sent by the Director of NIH Office of Human Subjects Research Protections (OHSRP), Jonathan Green, MD. This memorandum addressed the policy implementation of the 2018 Common Rule and other OHSRP policy changes, effective January 21, 2019. In this memorandum, it states that a witness to the signature of the written long form research consent at an NIH site (whether initially approved by an IRB before or after January 21, 2019) is no longer a requirement.

The federal regulations do not require a witness to be present for the signatures of the participant and investigator when a written long form research consent is used.

This memo and the memo distributed on January 15, 2019, supersedes applicable sections of the NIH policy regarding the use of a witness in the written long for consent (*NIH HRPP SOP 12 Requirements for Informed Consent 12.8.4.B and C, 12.9 and 12.15*). This is to alleviate our Investigators from non-compliance observations in monitoring and auditing reports.

The use of a witness is ***required*** for the consent process when using the short form research consent

Investigators are ***encouraged*** to have a second person (not obtaining informed consent) present during the entire informed consent discussion and, if applicable, the signature process. Investigators are further ***encouraged*** to document the presence and identity of that individual in the informed consent note placed in the medical record. This is also ***encouraged*** for both in person and telephone consent process.

For the written long form research consents that currently have the witness signature block, it is recommend to write, “N/A”, in the signature line.

If you have any questions, please contact Alissa Mun, ORSC Gini Guptill, ORSC, Nicole Grant OHSRP or Jonathan Green, OHSRP.

Thank you